

CLAIMS

What is claimed is:

- 5 1. An sterile apparatus comprising:
 a sterile buffer for hydration;
 a sterile device for use in a sterile application, the sterile device being immersed
in the sterile buffer; and
 a sterile package, wherein the sterile package encloses the sterile device and the
10 sterile buffer.
2. The apparatus of Claim 1, wherein the sterile device is a medical device.
3. The apparatus of Claim 1, wherein the sterile device is a sensor.
4. The apparatus of Claim 3, wherein the sensor includes a hydrated element.
5. The apparatus of Claim 1, wherein the sterile device is implantable.
6. The apparatus of Claim 1, wherein the sterile package is transparent.
7. The apparatus of Claim 1, wherein the sterile package is translucent.
8. The apparatus of Claim 1, wherein the sterile package is optically transmissive.
- 25 9. The apparatus of Claim 1, wherein the sterile device, sterile buffer and sterile package
have been sterilized using light.
10. The apparatus of Claim 1, wherein the sterile device comprises a gas-sterilized device.
- 30 11. The apparatus of Claim 1, wherein the sterile device comprises a liquid-sterilized device.

- 5

- 10

- 15

- 20

- 25

- 30

21. The method of Claim 20, wherein the biosensor comprises a biomolecule.

22. The method of Claim 21, wherein the biomolecule comprises a glucose oxidase enzyme.

23. An sterile apparatus comprising:

a sterile package; and

5 a sterile device for use in a sterile application, the sterile device being enclosed by the sterile package.

24. The apparatus of Claim 23, wherein the sterile device is a medical device.

10 25. The apparatus of Claim 23, wherein the sterile device is a sensor.

26. A sterile, implantable medical device for in vivo implantation comprising:

a sterile electronic circuit;

15 a sterile biological molecule for use as an agent in generating a signal to be used by the sterile electronic circuit; and

a sterile reservoir for housing the sterile biological molecule.

27. The device of Claim 26, further comprising a sterile package for packaging the device.

20 28. The device of Claim 27, wherein the device is packaged in a wet, sterile buffer solution.

29. The device of Claim 28, wherein the device requires no rinsing before implantation.

30. The device of Claim 26, wherein the sterile biological molecule is a sensor matrix
25 protein.

31. The device of Claim 26, wherein the sterile electronic circuit is an integrated circuit.

32. The device of Claim 26, wherein the sterile reservoir is a polymer.

33. The device of Claim 26, further comprising a permeable window covering the biological molecule.

34. The device of Claim 26, wherein the device may be used without an acclimation period.

35. The device of Claim 27, wherein the package is optically transmissive.

36. A method for producing a sterile, implantable medical device for in vivo implantation comprising:

preparing a device substrate for sterilization;
affixing non-biological elements to the substrate;
sterilizing the non-biological elements and the substrate with a gaseous sterilant;
affixing biological elements to the substrate;
sterilizing the biological elements with a wet sterilant;
packaging the substrate, the non-biological and biological elements into a wet

buffer; and

sterilizing the substrate, the non-biological and biological elements packaged in the wet buffer using light.

37. The method of Claim 36, wherein sterilizing the non-biological elements and the substrate with a gaseous sterilant comprises sterilizing the non-biological elements and the substrate with ethylene oxide.

38. The method of Claim 36, wherein biological elements are affixed to the substrate after sterilizing the non-biological elements and the substrate with a gaseous sterilant.

39. The method of Claim 36, wherein sterilizing the biological elements with a wet sterilant comprises sterilizing the biological elements with glutaraldehyde.

40. The method of Claim 36, wherein sterilizing the substrate, the non-biological and biological elements packaged in the wet buffer using light comprises sterilizing the substrate, the

non-biological and biological elements packaged in the wet buffer using a broad spectrum pulse light.

41. The method of Claim 36, wherein sterilizing the biological elements with a wet sterilant
5 comprises:

preparing a sterilization chamber;
preparing the wet sterilant;
pre-warming the wet sterilant;
loading sensors into the chamber;
10 exposing the sensors to the wet sterilant;
rinsing the sensors a first time; and
rinsing the sensors a second time.

42. The method of Claim 41 wherein rinsing the sensors a first time and a second time
15 comprises rinsing the sensors with a bicarbonate buffer.

43. The method of Claim 36, further comprising implanting the device in vivo.

44. The method of Claim 43, wherein implanting the device in vivo comprises implanting the
20 device in vivo without rinsing.